

CLAIMS

1. A method of treating a vulnerable plaque associated with a blood vessel of a patient, the method comprising:
 - 5 providing at least one gene therapy agent encoding at least one protein;
 - administering the gene therapy agent to a target cell population;
 - expressing the protein within the patient from a portion of the target cell population; and
 - 10 modifying the vulnerable plaque as a result of the protein expression.
2. The method of claim 1 wherein the gene therapy agent comprises a polynucleic acid selected from a group consisting of deoxyribonucleic acid and ribonucleic acid.
 - 15 3. The method of claim 1 wherein the gene therapy agent comprises a vector selected from a group consisting of a plasmid, retrovirus vectors, adenovirus vectors, Herpes Simplex vectors, Semliki Forest Virus vectors, and Sindbis virus vectors.
 - 20 4. The method of claim 1 wherein the gene therapy agent administration comprises at least one technique selected from a group consisting of injection, direct uptake, receptor-mediated uptake, intravenous administration, ingestion, electroporation, and precipitation.
 - 25 5. The method of claim 1 wherein the gene therapy agent is administered *in vivo* the patient.
 - 30 6. The method of claim 5 wherein the *in vivo* gene therapy is administered with a balloon catheter device.
 7. The method of claim 5 wherein the *in vivo* gene therapy comprises stenting the blood vessel adjacent the vulnerable plaque.

8. The method of claim 5 wherein the *in vivo* gene therapy is administered interstitially.

5 9. The method of claims 1 wherein the gene therapy agent is administered ex vivo the patient.

10. The method of claim 9 further comprising:

harvesting the cell population from the patient;

10 selecting for the portion of target cells capable of expressing the protein subsequent the administration of the gene therapy agent; and administering the selected cells into the patient.

11. The method of claim 10 wherein the selected cells are reintroduced

15 into a pericardial space of the patient.

12. The method of claim 1 wherein the protein is a collagen isoform.

13. The method of claim 1 wherein the protein is an A1 apolipoprotein

20 isoform.

14. The method of claim 13 wherein the A1 apolipoprotein is a mutant

Milano isoform.

25 15. The method of claim 1 wherein the target cell population comprises cells selected from a group consisting of muscle cells, vascular cells, hepatic cells, harvested patient cells, and donor cells.

16. The method of claim 1 wherein expressing the protein comprises

30 secreting the protein into a bloodstream.

17. The method of claim 1 wherein expressing the protein comprises

localized expression adjacent the vulnerable plaque.

18. The method of claim 1 wherein expressing the protein comprises modulating expression level with an expression cassette.

5 19. The method of claim 1 wherein modifying the vulnerable plaque comprises a modification selected from a group consisting of fibrous cap reinforcement, reduction of lipid pool size, modifying a lipid pool constitution, modifying an inflammation response, preventing vulnerable plaque formation, and preventing vulnerable plaque enlargement.

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20. A gene therapy agent for treating a vulnerable plaque associated with a blood vessel of a patient, the gene therapy agent comprising:

at least one polynucleic acid encoding at least one protein wherein administration of the gene therapy agent to a target cell population results in expression of the protein capable of modifying the vulnerable plaque.

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21. The gene therapy agent of claim 20 wherein the polynucleic acid selected from a group consisting of deoxyribonucleic acid and ribonucleic acid.

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22. The gene therapy agent of claim 20 wherein the protein is a collagen isoform.

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23. The gene therapy agent of claim 20 wherein the protein is an A1 isoform of an apolipoprotein.

24. The gene therapy agent of claim 23 wherein the A1 apolipoprotein is a mutant Milano isoform.

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25. The gene therapy agent of claim 20 further comprising a vector operable attached to the polynucleic acid.

26. The gene therapy agent of claim 25 wherein the vector is selected from a group consisting of a plasmid, retrovirus vectors, adenovirus vectors, Herpes Simplex vectors, Semliki Forest Virus vectors, and Sindbis virus vectors.

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27. The gene therapy agent of claim 20 further comprising a liposome sheathing the gene therapy agent.

28. The gene therapy agent of claim 20 further comprising an expression
10 cassette encoded in the polynucleic acid.